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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,225	03/26/2001	Peter Hawkins	109068	5800

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[REDACTED] EXAMINER

DO, PENSEE T

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1641

15

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/816,225	HAWKINS ET AL.
	Examiner	Art Unit
	Pensee T. Do	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 February 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 and 15-26 is/are pending in the application.
  - 4a) Of the above claim(s) 1-8 and 15-26 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 9-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All
    - b) Some \*
    - c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
    - a) The translation of the foreign language provisional application has been received.
  - 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Amendment Entry & Claim Status***

The amendment filed on February 27, 2003 has been acknowledged and entered as paper no. 14.

Claim 14 is cancelled. Claims 1-13, 15-26 are pending. Claims 1-8, 15-26 are non-elected. Claims 9-13 are examined.

### ***Withdrawn Rejection(s)***

Rejection under 112, 2<sup>nd</sup> paragraph in the previous office action is withdrawn herein.

### ***Newgrounds of Rejection(s)***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9, "magnetic filed" is unclear. Please clarify if that is a typo.

### ***Maintained Rejection(s)***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-11, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) further in view of Rapoport (US 5,978,694).

Kritz teaches a method of detecting an analyte comprising the steps of providing a sample comprising a marker, a binder (recognition element), said marker having material comprising an externally, inductively detectable relative magnetic permeability constant of at least about 600, said recognition element binds to or competes for binding with the analyte, said marker and said recognition element induce in a transducer comprising a coil a first inductance value when said analyte is absent from said sample and a second inductance value when said analyte is present in said sample. The recognition element (binder) is immobilized to a matrix (substrate) – see col. 6, lines 36-37. The sample containing the analyte and marker are added to the carrier. A competition or a sandwich reaction formed. The reaction was placed in a measuring coil and inductance changes noted. The inductance change in turn affected either the resonance frequency for an LC-circuit in which the coil was a part, or the balancing expressed as a voltage response, in a Maxwell Bridge in the coil was a part. The relationship between the change of resonance frequency in Hz, or the voltage difference in mV, is a linear relationship against the number of particles in the measuring solution, expressed as iron concentration. The molecular layer (recognition element) comprises an antibody/antigen and the second molecules are antigens or antibodies. (see col. 3, line 10-col. 4, lines 47; col. 5, line 10-col. 6, line 42; col. 9, lines 1-4).

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However, Kritz does not teach measuring the difference in resonant frequency when the substrate is exposed to a magnetic field and when the substrate is not exposed to the magnetic field; a solenoid coil.

Rapoport teaches a method for detecting in a sample a substance that responds to an applied magnetic field, such as paramagnetic substance. The sample is placed in an applied magnetic field, and the effect of the sample on a performance characteristic of a first electrical conductor is measured by the first measuring means and the value is displayed and/or optionally inputted to a data storage and analysis means. Subsequent measurements of this same performance characteristic of the first electrical conductor are made over time, either continuously or at pre-determined intervals. The performance characteristics are inductance, capacitance, etc. (See col. 3, lines 35-37). It is also desirable to compare the effect of the sample on the conductor in the presence of the applied magnetic field with the effect of the sample on the conductor in the absence of the applied magnetic field. (see col. 3, lines 20-26). Rapaport teaches a solenoid coil (figure 1).

It would have been obvious to one of ordinary skills in the art to measure the performance characteristic such as inductance of the sample in the presence and absence of the applied magnetic field as taught in Rapaport in the method of Kritz because that way the two measurements can be compared, taking into consideration the calibrations necessary to account for the differences, if any, in the performance characteristic of the first and second conductors. The corrected difference between the

two measurements is then a function solely of the presence of a substance in the sample, which responds to the applied magnetic field.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kritz et al. (US 6,110,660) further in view of Rapoport (US 5,978,694) further in view of Houghton et al. (US 5,679,342).

Kritz and Rapoport have been discussed above.

However, Kritz and Rapoport fail to teach a plastic strip as the substrate.

Houghton et al. teaches an assay wherein the receptor layer is immobilized on a matrix/solid support such as plastic strips, microliter plates, or any surface onto which antigen may be immobilized.(See col. 19, lines 45-51).

It would have been obvious to one of ordinary skills in the art that using matrix/solid support such as plastic strips is well known in the art. Thus, one of ordinary skills in the art would find it obvious to use plastic strips as taught by Houghton in the modified method of Kritz and Rapoport since Kritz suggested that the receptors are immobilized to a matrix and it is well known in the art that matrix for immobilizing receptor can be plastic strips for these plastic strips are polymers with compatible functional groups that immobilize the receptors securely on the strips and do not interfere with the molecular interaction of the receptor and the target analyte.

#### ***Response to Arguments***

The arguments filed on February 27, 2003 have been considered but not found persuasive.

Applicants amended the independent claim 9 to read wherein the tuned circuit is connected to a phase locked loop comprising a driver which generates a driving signal for driving the tuned circuit and a phase comparator for determining the phase difference between the driving signal and an output signal obtained from the tuned circuit, the difference in resonant frequency being determined by monitoring the performance of the phase locked loop. Applicants also traverse the rejection for the reason that Kritz teaches away from measuring resonant frequency. Furthermore, Applicants also argue that Kritz is incapable of detecting the paramagnetic marker particles recited in the claimed invention. Applicants also assert that because Kritz states that his method can only detect markers having a relative permeability of at least of about 600, Kritz would exclude paramagnetic markers.

Regarding the new limitations added, Rapoport teaches a device for detecting in a sample a substance, which responds to an applied magnetic field. The device comprises a first electrical conductor, which can be a coil (equivalent to the phase locked loop of the claimed invention). A performance characteristic of the first electrical conductor is conductance, inductance, resistance, and efficiency. The device further comprises a means for applying a known electromagnetic signal to the first electrical conductor to provide a change in which can be measured to indicate the presence of the substance of interest. Such means is equivalent to the "driver" of the claimed invention; the device also comprises a second electrical conductor (comparator) along with a second means for measuring one or more selected observable performance characteristics of said second electrical conductor. The differences in the performance

characteristics of the first and second electrical conductors are pre-determined, such that subsequent electrical measurements made can be calibrated to account for the differences. The two measurements are compared. The corrected difference between the two measurements is then a function solely of the presence of the substance in the sample, which responds to the applied magnetic field.

It would have been obvious to one of ordinary skills in the art to combine the method of Kritz with the device and method of Rapaport because Kritz teaches that inductance change in affect the resonant frequency and the relationship between the change of resonant frequency is a linear relationship against the number of particles in the measuring solution and Rapaport teaches that his device measures the inductance.

Regarding the argument about Kritz teaching away from measuring resonant frequency at col. 10, lines 41-44, Kritz simply just compares the results between measuring the resonant frequency of a particular "parallel" circuit containing the coil and a capacitor and using the Maxwell bridge approach.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., paramagnetic marker particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Paramagnetic markers particles have not been recited in the claims. Furthermore, applicants' assertion that markers having a relative permeability of at least of about 600 would exclude paramagnetic markers has no basis. There is not any

teaching proving that magnetic particles having relative permeability of about 600 are not paramagnetic markers.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee Do  
Patent Examiner  
April 18, 2003

*Christopher L. Chin*

CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800-1641

4/19/03